

# **Drug and Therapeutics Committee Training Course**

## **Session 2: Developing and Maintaining a Formulary**

### **Participant's Guide**

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## PURPOSE AND CONTENT

This session provides information about the formulary system and how it functions within the Drug and Therapeutics Committee (DTC). There will be discussion about implementing and maintaining a formulary, criteria for evaluation of drugs for the formulary, and a review of drug information resources.

As many as 70 percent of all drugs on the market today are either duplicative or of questionable value. This forces the health care system to institute its own complex screening methods to provide the most effective and cost-efficient drugs. This ample selection of drugs will only increase, as more drugs are produced by manufacturers and distributors in search of greater profits.

Benefits arising from the appropriate selection of drugs are numerous and well known and include improved drug therapy, decreased adverse drug reactions, improved efficiency in procurement/inventory management, and decreased overall health care cost.

## Objectives

Upon completion of this session, participants will be able to—

- Define the formulary system concept
- Identify criteria used for selection of drugs
- Understand basic formulary management principles
- Describe benefits of an effective formulary system
- Describe basic drug information resources for evaluating drugs

## Preparation

Read—

- Participant's Guide
- *Managing Drug Supply*, Chapter 10, "Managing Drug Selection"
- *Managing Drug Supply*, Chapter 11, "Treatment Guidelines and Formulary Manuals"

## **Further Readings**

American Society of Health-System Pharmacists. *ASHP Guidelines on Formulary System Management*. ASHP 1997–98.

Management Sciences for Health. *Manual for the Development and Maintenance of Hospital Drug Formularies*. Russia Rational Pharmaceutical Management Project. 1996.

World Health Organization. *The Use of Essential Drugs*. WHO Technical Report Series, #850. 1995.

## INTRODUCTION

Formularies and formulary systems are the backbone of the Drug and Therapeutics Committee. The formulary provides many benefits in providing improved patient care at decreased cost through improved selection and rational drug use. The formulary system also improves efficiency within the procurement and inventory management programs.

A comprehensive and active formulary system provides numerous benefits to hospitals and primary care clinics—

- Approved and efficacious drugs that all practitioners will be required to use:
  - Only the most effective and safe products will be available.
  - Available drugs will have been evaluated in a systematic manner.
  - Drugs will be chosen and approved to treat the disease states of the country.
  - Physicians will develop better experience with fewer drugs. Training will be easier as there will be fewer drugs on which to concentrate teaching activities.
- Drug therapy at a lower overall cost:
  - Ineffective high-cost drugs will not be available.
  - The most effective drug will be available to treat common health problems, resulting in fewer visits, improved outcomes, and subsequently lower costs.
  - Inventory cost will be reduced.
- Consistent supply of drugs:
  - Managing and regulating the number of drugs and improving the procurement and inventory management systems will result in the ordering of fewer drugs in larger quantities. These actions will enhance price competition and economies of scale with regard to quality assurance, procurement, storage, distribution, and dispensing and will subsequently lead to improved availability of drugs.
  - Less money will be wasted, making it possible to be more consistent in purchasing essential drugs and increasing availability.

The DTC and formulary system drive the entire health care system in the direction of improved cost-efficient care and patient outcomes. Every step in the formulary system will result in a more efficient system that will better utilize scarce health care resources.

## **Key Definitions**

**Formulary List**—Drugs approved for use in the health care system by authorized prescribers

**Formulary Manual**—The document that describes drugs that are available for use in the hospital and clinics (provides information on indications, dosage, length of treatment, interactions, precautions, contraindications, etc.)

**Formulary System**—The system of periodically evaluating and selecting drugs for the formulary, maintaining the formulary, and providing information in a suitable manual or list

## **FORMULARY MANAGEMENT PRINCIPLES**

The formulary is a periodically revised list of drugs that reflects the current judgment of the medical staff. The formulary system utilizes the medical and pharmacy staff to evaluate, appraise, and select from among the numerous available drugs those products that are the most efficacious, safe, of adequate quality, and at a reasonable price. When completed, the formulary should conform to the following principles:

- Drugs should be selected based on the needs of the community; they should treat the diseases and conditions that have been identified locally.
- Drugs selected for the formulary are “drugs of choice.”
- The formulary list should have a limited number of drugs, only those necessary to provide for the needs of the hospital or clinic; duplication of agents that have therapeutic equivalence should not occur.
- Drugs need to be selected based on explicit criteria that include proven efficacy, safety, quality, and cost.
- The formulary must be consistent with any national or regional formulary or approved standard treatment guidelines.

## **Maintaining a Formulary**

The formulary maintenance process is dependent on two key components, additions/deletions of drugs and therapeutic drug class reviews. Additions and deletions should be handled following specific policies and procedures developed for the DTC. A transparent methodology must be developed for these important decisions concerning addition or deletion of a drug. See the next section for recommended criteria for adding drugs to the formulary.

Routine drug class reviews are an important activity to maintain the formulary. The drug class review involves the review of a complete section of drugs (e.g., cephalosporin antibiotics). This review would evaluate current drugs on the formulary in a systematic manner so that the entire formulary is reviewed over a two- to three-year period. This is a cumbersome task, but it will provide the necessary review and analysis of formulary drugs that is so important in a profession that is changing rapidly. Any new drugs that would offer an advantage over the current selections would be evaluated and considered for the formulary. Drugs that are no longer used or lack sufficient evidence of efficacy, safety, and quality should be recommended for deletion. Drugs that no longer meet the criteria for being cost-effective should be evaluated and deleted when an acceptable alternative is identified.

In order to maintain the formulary, regularly scheduled meetings must be established and attended by committee members. Ideally, the committee would meet monthly or, at the very least, every four months. Longer meeting intervals will necessitate too many agenda items and make it very difficult to accomplish the necessary activities.

Each meeting should have an agenda, one that describes exactly what will be addressed during the meeting. Minutes are taken and reviewed at the next scheduled meeting.

Typically, an effective committee will provide the following at each session:

- Action on newly requested drugs and deletions  
(Addition of a new drug should lead to the deletion of a similar drug on the formulary in most cases.)
- Systematic review of therapeutic groups/classes by a competent physician or pharmacist
- Review of programs to identify and resolve drug use problems

Without this review process, the formulary may become a collection of older drugs that may not reflect the most effective products available. It is the DTC's responsibility to see that review is accomplished on a regular basis.

## **PROCESS FOR SELECTION OF A NEW DRUG**

Selection of drugs for the formulary should follow carefully considered policies and procedures for determining the most useful drugs. These policies should be followed routinely and accurately each time an evaluation is needed. The following process is recommended for selection of new drugs:

1. A request for addition or deletion of a drug to the formulary, which can be made only by a physician or pharmacist, is made through completion of a Request for Addition/Deletion form. Information needed from the physician or pharmacist includes—

- List of specific pharmacological actions of the drug
  - Information on why the drug is superior to current formulary drugs
  - Specific literature support for use
  - Background on any financial support received from the supplier or other organization
2. Obtain drug information resources. These should include primary literature, international newsletters, standard treatment guidelines, textbooks, and Internet sources. All sources of information must be credible and unbiased.
  3. Perform the evaluation using established criteria (see page II-7).
  4. Write the drug information monograph. The drug monograph should include details about the drug obtained from several information sources. At a minimum, the monograph should include—
    - Pharmacology
    - Pharmacokinetics
    - Efficacy compared to placebo and other drugs
    - Clinical trial analysis
    - Adverse drug reactions
    - Drug interactions
    - Cost comparison
    - Sources of supply (to ensure availability)
  5. Develop formulary recommendations. After a thorough research of the literature, the DTC should formulate recommendations concerning the drugs on the evidence-based drug information. Recommendations should include dosage forms and strengths that will be purchased. If a specific manufacturer or supplier is necessary because of bioavailability problems, then this should be addressed in these recommendations. Specific guidelines for administration or use should also be placed in these formulary recommendations.
  6. Obtain expert opinions and recommendations. These should be obtained from knowledgeable and respected physicians and pharmacists. Opinions should complement the information provided in a drug information search.
  7. Make a formulary decision (at the DTC meeting). Information should be presented to the DTC at a regularly scheduled meeting. The DTC must vote on the recommendations as presented by the individual who performed the drug evaluation.
  8. Disseminate the results of the evaluation and DTC's recommendations. Results of the DTC actions and recommendations must be disseminated to the health care staff in the form of meeting minutes, newsletters, or department meetings.



## **CRITERIA FOR SELECTION OF DRUGS**

Selecting drugs for the formulary is the most important function of the formulary system. The process is multifactorial and ultimately brings the best drugs to the health care system. The following represent major criteria to be considered when evaluating all new requests for addition to the formulary:

- Disease patterns of the country
- Efficacy, relative efficacy, effectiveness
- Safety
- Quality
- Cost
- Drugs that are well known
- Health system personnel and equipment available to manage the drug
- Financial resources available

### **Disease Patterns**

The morbidity of the region needs to be assessed carefully before adding or deleting any drugs. Formulary drugs should be approved only after confirmation of actual need to treat the known diseases and medical conditions of the community. Standard treatment guidelines must be reviewed to determine appropriate drugs for the medical conditions listed in the guideline.

### **Efficacy**

Proven efficacy is one of the most important criteria in selecting new drugs for the formulary. The methods to accomplish a thorough evaluation of efficacy are presented in later sessions.

Information that accompanies a new drug, including the package insert, drug company literature, and advertisements, may not always provide unbiased information for evaluating the drug in question. A comprehensive review of journal articles, especially randomized controlled trials, will provide the best unbiased information. Reviewing information in texts and international newsletters will provide the reviewer with additional supporting information concerning efficacy. Careful evaluation of all sources must be done to ensure that evidence of efficacy is supported by the literature and is unbiased and accurate.

### **Safety**

Determining the safety of a drug requires close attention to established information on the drug as well as current postmarketing surveillance (provided by the manufacturer or drug regulatory agency) of the drug's safety record. Drugs with excellent safety records are necessary for the

formulary, but are not always possible to obtain. A careful assessment of risk-benefit will be necessary for all drugs before they are added to the formulary.

The cost of treating adverse drug reactions is very high, both in monetary terms and in lowered patient quality of care. Every effort must be made to evaluate a drug's safety record and its potential for adverse reactions. More information concerning safety will be presented in Session Four, "Assessing and Managing Drug Safety."

## **Quality**

The quality of a drug that is requested for the formulary is very important. Poor-quality drugs that are administered to patients may have adverse effects, including—

- Lack of therapeutic effect
- Toxic and adverse reactions
- Waste of financial resources
- Loss of credibility of the health care services

Before adding a drug to the formulary it is necessary to determine if the following characteristics of quality can be assured by the health care system:

- Identity—Active ingredients are in the dosage form.
- Purity—The drug contains no contaminants.
- Potency—The drug has enough, but not too much, of the active ingredient.
- Uniformity of dosage form—The consistency, color, shape, and size of tablets, capsules, creams, and liquids do not vary from one dose to the next.
- Bioavailability—Bioavailability refers to the speed and completeness with which a drug administered in a specific form enters the blood stream; different manufacturers of the same drug may have different bioavailability.
- Stability—A drug product must retain its properties within specified limits in order to be useful.

The purpose of a quality assurance program for hospitals and clinics is to ensure that every drug reaching a patient is safe, effective, and meets quality standards. A comprehensive quality assurance program includes both technical and managerial activities from selection to patient use. Many areas within a health care system may be involved with quality assurance, including procurement, pharmacy, medical, and nursing departments, as well as the DTC.

Ensuring quality of a product is twofold:

1. *Obtaining* quality products that are safe and effective through structured selection and procurement methods
2. *Maintaining* quality products through the appropriate storage, distribution, monitoring, and prescribing methods

A comprehensive drug quality assurance program requires procurement, pharmacy, warehousing departments, and the DTC to ensure the following:

- Suppliers with acceptable quality standards are selected.
- Minimum quality standards are met or exceeded and appropriate testing of the end product is performed.
- Repackaging of supplies maintains quality.
- Storage and transportation conditions are adequate.
- Product quality concerns reported by prescribers, dispensers, and consumers are documented, investigated, and resolved.

More information on drug quality will be presented in Session Five, “Drug Quality Assurance.”

## Cost

The cost of a drug in relation to its benefits is a very important consideration with any new drug. A drug with questionable benefits at a high cost would have an unfavorable cost-benefit ratio. However, a new antihypertensive drug with good comparative efficacy, decreased incidence of adverse drug reactions, and a lower overall cost than current drugs on the formulary would represent an excellent cost-benefit relationship. This drug would therefore have a favorable status for being added to the formulary. However, when a new drug with equal efficacy and possibly fewer adverse side effects at a higher cost is requested, the decision becomes more complicated. More information on determining the cost of pharmaceuticals is presented in Session Six, “Evaluating the Cost of Pharmaceuticals.”

## Drugs That Are Well Known

Ideally, drugs that are selected for the formulary are ones that are well known, have been on the market for years, and have clinical experience to support their pharmacological profiles. This is not possible for all drugs added to the formulary, but it should be one of the basic parameters to consider when adding a drug.

## **Availability of Appropriate Personnel**

It is important to have available health care personnel who have the experience, training, and credentials necessary to utilize these drugs. Any drug, no matter how effective and safe, must be measured against the personnel who will actually be using the drug. A system of layered prescribing authority is useful when the health care system has practitioners with different levels of experience and qualifications.

## **Availability of Financial Resources**

The health care system must have at its disposal a sufficient amount of money to actually purchase and maintain the drug for an indefinite amount of time. A thorough cost analysis is therefore necessary before the drug is actually accepted for the formulary. If the resources are not available for the consistent procurement of a new drug, then it should not be accepted. Intermittent purchase of a drug that the system cannot afford only serves to foster poor medical services with little or no continuity of care.

## **NONFORMULARY DRUGS**

Most formulary systems are designed as an “open” system. The open system allows for the introduction of nonformulary drugs on a limited basis, usually for a single patient use. A closed system reflects the DTC’s choice to exclude all nonformulary drugs from being available in any form.

Nonformulary drugs are necessary, in limited amounts, for patients who require specialized treatments or patients who have been stabilized on drugs from practitioners outside of the health care system.

Control of nonformulary drugs is important as an open system will invariably become problematic and impede the system of formulary management. Numerous nonformulary drugs will be costly and, because they may not have received the complete evaluation process, they may be less than effective or unsafe. Management of nonformulary drugs includes—

- Limiting the number of nonformulary drugs
- Limiting access to appropriate prescribers
- Reviewing frequently

Policies and procedures on how these drugs will be purchased are necessary and close follow-up of all nonformulary drugs by the DTC is warranted in order to limit their use.

## **RESTRICTED DRUG USE**

Restricted drugs include those products that fill a particular need by a specialty within the health system. These drugs need to be defined by the DTC in order to limit their use. Some examples of restricted drugs and their applicability include—

- Certain antibiotics for infectious diseases
- Antipsychotic drugs for use by mental health professionals
- Antineoplastic products for use by physicians with specialized knowledge of these drugs

The use of restricted drugs requires that there be close monitoring and evaluation of these drugs. Monitoring of restricted drugs should include determining that appropriate patients are receiving the drugs and that authorized medical staff are prescribing and providing follow-up for patients on these medications.

## **INTERNATIONAL NONPROPRIETARY DRUG NAMES**

The use of international nonproprietary drug names (generic names) is encouraged for all listings in the formulary, evaluation monographs, and all other communications about drugs. This international nonproprietary name is the drug's official name, regardless of who manufactures or markets it.

Formulary systems that utilize the generic name system will find that it makes for a more efficient system and causes less confusion about the actual products listed. Instead of dealing with 10 to 20 or more trade names for each drug entity, there will be only one. The system will also enhance any therapeutic or generic substitution programs that may exist.

## **INFORMATION RESOURCES FOR EVALUATING DRUGS**

Adequate resources to obtain information and to evaluate the efficacy, safety, quality, and cost of a drug are essential. This section provides basic information concerning well-known drug information sources.

Medical information sources include three categories: primary, secondary, and tertiary resources.

- Primary literature
  - Includes journal articles and unpublished studies that may be obtained from journals and services that provide the entire article
  - Represents the most complete information about a subject because all the data discussed in the article are available to the reader

- Disadvantages include that the reader must have skills to evaluate the article and the amount of time necessary to actually read and analyze
- Secondary literature
  - Includes indexing and abstracting services that provide abbreviated reviews of articles
  - Usually published in newsletters, CD-ROM databases, and online services
  - Advantages include readily accessible and easy-to-read information
  - Disadvantage is the long time period between publication and the republication in the newsletter or abstracting service
- Tertiary sources
  - Include published textbooks, which can be an excellent source of information if reputable and current sources are used
  - Advantages include readily accessible information and short time in reading and assimilating the information
  - Disadvantages include the lack of access to the original information sources, bias introduced by the writers of the text, and outdated information provided because of long delays in publishing a text

Representative journals and texts are listed below. There are others, but these are generally considered to be representative of excellent resources.

- Primary resources
  - *British Medical Journal*
  - *Lancet*
  - *New England Journal of Medicine*
  - *Journal of the American Medical Association*
  - *Annals of Internal Medicine*
  - *American Journal of Health-System Pharmacy* (AJHP)
- Secondary resources
  - *Medical Letter*
  - *Australian Prescriber*
  - *Journal Watch*
  - MEDLINE and EMBASE abstracts
  - Cochrane Library abstracts and evaluations
  - International Pharmaceutical Abstracts

- Tertiary resources
  - *Martindale: The Extra Pharmacopoeia*
  - *British National Formulary*
  - *United States Pharmacopeia Dispensing Information (USP DI) Drug Information for the Health Care Professional*
  - American Hospital Formulary Service (AHFS)
  - *Facts and Comparison*
- Internet resources
  - MEDLINE—[www.nlm.nih.gov](http://www.nlm.nih.gov)
  - World Health Organization (WHO)—[www.who.int](http://www.who.int)
  - Centers for Disease Control and Prevention (CDC)—[www.cdc.gov](http://www.cdc.gov)
  - National Institutes of Health (NIH)—[www.nih.gov](http://www.nih.gov)
  - Food and Drug Administration (FDA)—[www.fda.gov](http://www.fda.gov)
  - Cochrane Collaboration—[www.cochrane.org](http://www.cochrane.org)
  - Agency for Healthcare Research and Quality (AHRQ)—[www.ahrq.gov](http://www.ahrq.gov)

Ideally, the hospital will have a drug information center to handle requests concerning adding drugs to the formulary. If not, a pharmacist or a physician can provide the necessary evaluations given the time and at least some of the resources listed above. Pharmacists will find that by using as many of the resources as possible they will be able to provide the review in a comprehensive manner.

Using information from pharmaceutical companies requires the reader to exercise some caution. These companies may provide less than unbiased information and this must be screened before use. Many articles and documents may appear to provide usable information, but frequently the information presented has a particular bias for the company's product.

It is worth taking note of the phenomenal changes that are occurring in the drug information resources on the Internet. Although this communication method may not be available to pharmacists or physicians in many parts of the world, it is something to establish if at all possible. The information sources on the Internet are virtually endless. The quality of drug evaluation reports can improve and, with experience, the speed of providing an evaluation will also improve. The Internet can also provide very poor information so it must be used with caution.

## FORMULARY MANUAL

The formulary manual is the publication that brings all of the data concerning the formulary together in a manual or pamphlet. There is no set standard on how this document is arranged or what it includes, but ideally it contains both alphabetically and therapeutically arranged lists of the formulary drugs and a section on drug usage that includes doses, contraindications, side effects, drug interactions, and price. The manual should include a section on the drugs of choice and alternates for treating the medical conditions of the region.

This manual is not intended as a book to place on the shelf. It should be pocket-sized to allow practitioners to carry it with them at all times. The design of the manual requires that it be easy to use with appropriate indexing to facilitate location of necessary information.

The following items should be available in a comprehensive formulary manual. The DTC would have to evaluate these items and include only the most appropriate in its formulary manual.

Basic information:

- Formulary list or essential drugs list
  - Alphabetical and therapeutic category lists
- Brief information about each drug (drug monograph)
  - Generic name
  - Dosage and strengths
  - Indications
  - Contraindications
  - Precautions
  - Side effects
  - Dosage schedule
  - Instructions and warnings
  - Drug, food, lab interactions

Miscellaneous information:

- Supplementary information for drugs
  - Price
  - Regulatory category
  - Storage guidelines
  - Patient counseling information
  - Labeling information
  - Brand names and synonyms
- Prescribing and dispensing guidelines
  - Rational prescribing techniques
  - Principles of prescription writing
  - Guidelines on quantities to be dispensed
  - Control drug requirements
  - Adverse drug reaction reporting requirements
  - Dispensing guidelines
  - List of precautionary labels
  - Drug interaction tables
- Treatment protocols
  - IV drug administration guidelines
  - Drugs used in pregnancy and lactation



- Drugs used in renal failure
- Poison guidelines
- Prescribing for the elderly
  
- Other components
  - Metric tables
  - Adverse drug reaction form
  - Product quality report form
  - Formulary request form
  - Nonformulary drug request forms
  - Abbreviations

A comprehensive index of all items in the formulary manual is essential. Because of the complexity of this document, an index will facilitate use by practitioners and ultimately improve efficiency within the health care system.

## **ACTIVITIES: ADDING NEW ANTIMICROBIALS TO THE FORMULARY**

### **Activity 1.**

The participants will break up into groups of five individuals. Each group will elect a leader who has some experience in the management of formulary systems. The group leader will report the overall findings of the group concerning this activity.

Your DTC is considering a new antibiotic for the formulary. This antibiotic is very similar to a formulary product, cefotaxime, a third-generation cephalosporin. It would be used in the emergency room for managing febrile children with the diagnosis of acute respiratory infection (ARI) or otitis media (OM) who appear toxic and are candidates for admission to the hospital. This drug is an injectable at a very high cost of \$5.50 per dose. The physician requesting this drug states that although it is very expensive, use of the drug will decrease overall cost because hospitalizations will be decreased with appropriate use. The drug would be used by mid-level providers who staff the emergency room at night. The hospital has a very tight budget, relies on donors for a significant amount of the drug supply, and frequently runs out of medication because of poor supply management practices.

Other drugs available in the hospital for this particular medical condition include amoxicillin, cephalexin, co-trimoxazole, and chloramphenicol.

- What criteria are necessary to evaluate this drug for addition to the formulary?
  
- Utilizing the criteria discussed in this session, what major concerns do you have before adding this drug to the formulary?
  
- What drug information resources would be used to analyze this drug for the DTC? Which source would be the most useful?

## **Activity 2.**

The participants will break up into groups of five. Each group will select a leader who has experience with a DTC. The group will review the activity, identify problems with the scenario, and make recommendations for evaluating the drug in question for the formulary.

You are a new member of the DTC for your hospital. A new antimicrobial has been requested by one of your physicians. This antimicrobial has a broad spectrum of activity that includes activity against most common gram-positive and many gram-negative bacteria. The drug is a suspension that is given four times daily for 10 days.

The drug is heavily promoted, by a pharmacy company representative, for treating many different pediatric infections. The cost is high, \$2.00/day, but it is required (according to the requesting physician) because of a high incidence of antimicrobial resistance in the hospital. This antibiotic is typically used for children with acute otitis media, sinusitis, and bronchitis. Safety of this drug has not been fully evaluated.

Other drugs for these problems that are available on the formulary include amoxicillin, co-trimoxazole, and cephalexin. Typically the DTC has provided very little evaluation of new drugs; a physician's recommendation was enough for approval by the committee.

- What are some important considerations when adding a drug such as this to the formulary?
- What are some obvious potential drug use problems that are depicted in this activity?
- What responsibility does the DTC have to the health care system concerning the addition of drugs, especially antibiotics, to the formulary?
- What functions of the DTC are needed to fully address the antibiotic request?

## **Summary**

The formulary system adds an important component to the DTC and the health care system. A system of evaluating and selecting the most appropriate drugs for the formulary will bring numerous benefits. These include rational drug use, improved health care outcomes, improved efficiency in the procurement and inventory management systems, regular supply of essential drugs, and a significant decrease in overall health care cost.

Listed below are some key points to remember concerning the starting of a formulary system or maintaining one for years to come—

- Write detailed policies and procedures concerning the functions of the formulary system.
- Evaluate drugs carefully to obtain the best drug at a favorable cost.

- Review the formulary in a systematic manner to ensure it is current.
- Keep nonformulary drugs to a minimum.
- Restrict drugs to appropriate practitioners.
- Keep on hand up-to-date drug information resources that provide unbiased comparative information.
- Enlist the support of key policymakers and influential health professionals to advocate for the DTC and formulary system.
- Keep the formulary process ethically correct—the DTC and especially the formulary system must tolerate no influence or pressure from pharmaceutical manufacturers or suppliers concerning any product that is considered for addition to or deletion from the formulary.